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AN APPLICATION OF THE DOMINANT FIRM MODEL TO THE CANADIAN DIAZEPAM MARKET[1]

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Introduction

Several commissions of inquiry, initiated by the federal government during the 1960's, found that Canadian drug prices at that time were high in comparison with prices prevailing in most other industrialized nations. In 1963, the Restrictive Trade Practices Commission, in 1964, the Hall Commission on Health Services and, in 1967, the Special Committee on Drug Costs and Prices (the Harley Committee) published similar findings:

> "Your Committee confirms the previous findings now on public record; and it has come to the inescapable conclusion that drug prices in Canada are in fact high and that every fair and reasonable step should be taken to reduce these prices".[2]

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[1] This paper has benefited immensely from the comments and suggestions of Don McFetridge. Constructive comments were also received from Fenton Hay, Nick Hunking, Jim Keon and David Duck. Excellent computer assistance was provided by Guy Roberge. The author is an employee of the Research and International Affairs Branch of Consumer and Corporate Affairs Canada. It should be noted that this paper does not necessarily represent the viewpoint of the Department.

[2] Second and Final Report of the Special Committee on Drug Costs and Prices, p. 15, Queen's Printer, Ottawa, 1967.

The views presented in this paper are those of the authors and do not necessarily reflect the views or position of the Department of C.C.A.

The government commissions had all concluded that patent protection was an important source of market power in the industry and, consequently, one of the major recommendations of the Harley Committee was that the Canadian Patent Act should be amended to allow the Commissioner of Patents to issue compulsory licenses permitting the importation and sale of patented pharmaceuticals by competitors of the patent holder. Compulsory licenses to import were recommended as an addition to compulsory licenses to manufacture, which the Commissioner had been empowered to grant since 1949.

In June of 1969, the Canadian Patent Act was amended by Parliament to implement the Harley Committee proposal. From that date to the present, the Commissioner has considered 291 applications for compulsory licenses to import. Of these, 246 were granted, 3 were rejected, and 15 submissions were withdrawn. 27 Applications are still pending. In all of the cases where the application was granted, the Commissioner fixed a royalty of 4% of the wholesale selling price to be paid by the licensee to the patent holder.

A number of other recommendations made by the Harley Committee were also put into practice. The Trade Marks Act was altered so as to facilitate the operation of compulsory

licensing under the Patent Act. The Pharmaceutical Industrial Assistance Program was set up to give financial assistance to independent Canadian drug manufacturers. The QUAD[3] review was published and distributed to all physicians, veterinarians, dentists and pharmacists in Canada. The main objective of this publication was to make medical professionals aware of differences in manufacturers' prices for chemically equivalent drug products meeting federal quality and safety standards. At the same time, quality surveillance of imported drugs was strengthened in order to ensure that drugs imported under the amended Patent Act would be of the same quality as drugs already sold in Canada. The customs duties on imported drugs were reduced and amendments were made to the Anti-dumping Regulations to facilitate entry of drugs into Canada. All of these initiatives were complementary to the enactment of the compulsory licensing provisions.

Another recommendation made by the Harley Committee was that the provinces should consider implementing measures to increase competition at the retail level. As a result of this recommendation, most provinces have introduced generic substitution legislation. Under the legislation, pharmacists

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[3] QUAD stands for Quality Assessment of Drugs and is published by the Health Protection Branch of National Health and Welfare.

are permitted (in some instances required)[4] to dispense lower priced, generically equivalent drug products unless the physician writes "no substitution" on the prescription. As well, most provinces now publish formularies, similar to the QUAD review, which serve to make physicians and pharmacists aware of price differences for chemically equivalent products. Most provinces have also introduced some form of drug benefit plan or insurance and have encouraged pharmacists to charge flat rate dispensing fees rather than a percentage markup on the drug acquisition cost.

The objective of this study is to measure the efficacy of these government initiatives in lowering the price of the leading brand of diazepam over the period 1971 to 1979.

Diazepam is a mild tranquilizer and muscle relaxant discovered by Dr. Leo Sternback, a research chemist employed by Hoffman-Laroche in the United States. Diazepam was introduced into Canada in 1963 by Hoffman-Laroche Limited under the brand name "Valium". From 1963 to 1970, Roche held a monopoly over the sale of diazepam by virtue of its patents. For several years, Valium was the largest selling prescription

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[4] In Saskatchewan, for example, generic substitution is compulsory. In Ontario, the government will only reimburse the pharmacist for the lowest priced equivalent brand. This does not apply to sales paid for by private citizens.

pharmaceutical in Canada and in 1976 was still the third largest selling pharmaceutical. Sales for 1979 at wholesale prices were approximately $4,822,000.[5] By virtue of its patents over diazepam and another tranquilizer (chlordiazepoxide), Hoffman-Laroche was the leading pharmaceutical company in Canada in terms of sales in 1969.

In the spring of 1970, Frank Horner Ltd. entered the diazepam market after obtaining a compulsory license to import from the Commissioner of Patents. Since that time, 12 compulsory licenses have been issued for the importation and sale of diazepam. This paper will examine the effects which this competition had on the price of diazepam as marketed by Hoffman-Laroche.

Theory

The theoretical model employed is a modification of the dominant firm "inverted umbrella".[6] The simple model

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[5] IMS Ltd., Drug Store and Hospital Report, Dec. 1979.

[6] See
Stigler, G., "The Dominant Firm and the Inverted Umbrella", Journal of Law and Economics, Oct. 1965.
Worcester, D.A., "Why Dominant Firm Decline", Journal of Political Economy, Aug. 1957.
Patinkin, D., "Multiple Plant Firms, Cartels and Imperfect Competition", Quarterly Journal of Economics, Feb. 1947.

assumes that fringe demand is perfectly price elastic at the dominant firm price or at some fraction (1-K) of dominant firm price (where K<1 represents the value of goodwill accruing to the dominant firm). This simple theory is essentially a theory of fringe supply which predicts declining market shares and prices over time for the dominant firm.

For our present purposes, it is necessary to modify the simple model to allow for shifts in the demand function facing fringe producers. It is reasonable to expect, for example, that advertising by fringe firms will shift this demand function. Similarily, provincial generic substitution legislation can be expected to alter the degree of dominant firm goodwill by transferring some decision making power from physicians to pharmacists.

It is assumed that the fringe firms are competitive. In the case of diazepam, one firm, Horner, was the sole member of the fringe from 1970 to 1973. Two more members entered the fringe in 1973, two in 1974, one in 1975 and one in 1978. In order for the fringe price to be a competitive price, it is necessary to assume that Horner did not command any market power when it was alone in the

fringe, that is, that Horner could not raise price above marginal cost. Some support for this assumption can be gained from the fact that Horner held less than 12 per cent of the relevant market from 1970 through 1973.

It is assumed that each fringe firm operates under the same cost function. The pharmaceutical industry in Canada is basically a final assembly operation. Raw bulk chemicals are imported, pressed into tablets or capsules, bottled and then packaged for final sale. In the case of fringe supply, all chemicals are purchased on an open world market (this was the intent of the compulsory license to import provision in the Patent Act). All producers face the same labour costs and, as all fringe firms entered the market between 1970 and 1978, it is assumed that all had access to the same technology. In a perfectly competitive market with the same cost functions, each firm will produce the same output. Consequently,

$$(1) \qquad Q_F^S = N(q_F^S)$$

where Q_F^S = fringe quantity supplied

N = number of fringe firms

q_F^S = quantity supplied by the individual fringe firm

The amount supplied by each fringe firm will be a function of own price (P_F) plus a number of shift variables (X_F). For ease of mathematical exposition, a generalized version of the Cobb-Douglas function is postulated throughout.

$$(2) \qquad Q_F^S = N(d_0 P_F^{d_1} X_F^{d_2})$$

Fringe quantity demanded (Q_F^D) is a function of fringe price (P_F) and several shift variables. One of these, price of the dominant firm (P_D) is identified explicitly while other shift variables are denoted by Z_F.

$$(3) \qquad Q_F^D = C_0 P_F^{C_1} Z_F^{C_2} P_D^{C_3}$$

Competitive equilibrium requires that fringe quantity supplied equals fringe quantity demanded. Taking logs of (2) and (3), equating and solving for $\ln P_F$ yields:

$$(4) \qquad \ln P_F = \frac{(\ln C_0 + C_2 \ln Z_F + C_3 \ln P_D)}{d_1 - C_1} - \frac{(\ln N + \ln d_0 + d_2 \ln X_F)}{d_1 - C_1}$$

Similarily, dominant firm demand in terms of price will be a function of own quantity (Q_D) and several shift variables. One of these shift variables, P_F, is denoted

explicitly while the rest are denoted by Z_D.

$$(5) \qquad P_D = a_0 \; Q_D^{a_1} \; Z_D^{a_2} \; P_F^{a_3}$$

and

$$(6) \qquad MR_D = (1+a_1) \; a_0 \; Q_D^{a_1} \; Z_D^{a_2} \; P_F^{a_3}$$

Dominant firm cost is a function of own quantity supplied and any variable shifting dominant firm costs.

$$(7) \qquad C_D = b_0 \; Q_D^{b_1} \; X_D^{b_2}$$

and

$$(8) \qquad MC_D = b_1 \; b_0 \; Q_D^{b_1 - 1} \; X_D^{b_2}$$

Equating MR and MC, substituting profit maximization output into (5), and taking logs yields:[7]

$$(9) \qquad \ln P_D = A + \frac{a_2 \; (b_1-1)}{b_1-a_1-1} \ln Z_D + \frac{a_3 \; (b_1-1)}{b_1-a_1-1} \ln P_F - \frac{b_2 \; a_1}{b_1-a_1-1} \ln X_D$$

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[7] Where $A = \left(\frac{b_1 - 1}{b_1 - a_1 - 1}\right) \ln a_0 + \left(\frac{a_1}{b_1 - a_1 - 1}\right) \left(\ln (1 + a_1) - \ln b_1 - \ln b_0 \right)$

substituting (4) into (9) produces the reduced form equation.[8]

$$(10) \quad \ln P_D = e_0 + e_1 \ln Z_D + e_2 \ln X_D - e_3 \ln X_F + e_4 \ln Z_F - e_5 \ln N$$

Both fringe supply, and dominant firm supply shift variables (X_F and X_D respectively), are wages, raw material costs and technology. Technology is assumed not to change over the period studied. As both dominant and fringe firms "assemble" their final dosage forms in Canada, wages are assumed the same for both entities.

Fringe firm demand is shifted by fringe firm advertising. Dominant firm demand is shifted by dominant firm advertising. Fringe firm demand is also shifted by changes in the degree of perceived product differentiation which has come about principally as a result of provincial substitution legislation. Both demand curves are also shifted by the introduction of new competing chemicals within the same therapeutic class (in the present case, the introduction of new chemicals which act as tranquilizers).[9]

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[8] Where, for example: $e_1 = \dfrac{a_2 \ (b_1 - 1) \ (d_1 - C_1)}{(b_1 - a_1 - 1) \ (d_1 - C_1) - a_3 \ (b_1 - 1) \ C_3}$

[9] See Reekie, D.W., Price and Quality Competition in the United States Drug Industry for a discussion of the effects of entry in the same therapeutic class.

This discussion suggests an equation of the following form:

$$(11)\quad \ln P_D = g_0 + g_1 \ln N + g_2 \ln PROV + g_3 \ln AD + g_4 \ln AF + g_5 \ln W + g_6 \ln FRM + g_7 \ln DRM + g_8 \ln TCE + \mu$$

where P_D = price of the dominant firm

N = number of fringe producers

PROV = provincial substitution legislation

AD = advertising by dominant firm

AF = advertising by fringe firms

W = wage index for pharmaceutical workers in Canada

FRM = fringe firm raw material price

DRM = dominant firm raw material price

TCE = new entry by drugs in the same therapeutic class

It is expected that an increase in the number of fringe firms, by shifting the fringe supply curve, will lead to a decrease in the price of the dominant firm and, hence, it is expected that the value of g_1 will be negative. Similarily, it is assumed that the introduction of provincial substitution legislation will act to shift outward the fringe demand curve and, hence, the coefficient, g_2, is also expected to be negative. The coefficient for fringe advertising is more difficult to predict. Fringe advertising will act to shift

outward the demand curve for fringe products but may also act to shift out the demand curve facing the diazepam industry as a whole. Depending on which effect predominates, the residual demand curve facing the dominant firm may shift to the left or right and g_4 may, therefore, be positive or negative. The same uncertainty does not apply to advertising by the dominant firm. This should act to shift out both dominant firm demand and diazepam industry demand. It is, therefore, expected that the coefficient g_3 will be positive. An increase in wages should shift the fringe supply curve inward and will raise marginal cost for the dominant firm. It is, therefore, expected that the coefficient g_5 will be positive. An increase in dominant firm raw material costs should increase dominant firm marginal cost and, hence, g_7 is expected to be positive. Similarily, an increase in fringe raw material costs should lead to an increase in the price of the dominant firm and g_6 is expected to be positive. The entry of new chemical entities in the same therapeutic class will act to shift the diazepam industry demand curve to the left and may make the curve more elastic. Both of these effects would lead to a lower dominant firm price and the coefficient g_8 is expected to be negative.

Both N, the number of fringe firms and TCE, new entry into the therapeutic class, are largely pre-determined in the model due to institutional lags. In particular, all drugs

marketed in Canada must first obtain clearance[10] from National Health and Welfare. This procedure requires extensive testing of the safety and efficacy of the product which can take up to 18 months. Of course, any firm is free not to market its product after obtaining clearance but, given the magnitude of expenditures required,[11] it is likely that the decision to enter the market is made before any tests are undertaken. The decision to enter is, therefore, a function of price in some past period plus expectation of price at the date of entry. The same clearance procedure is required for new drugs (TCE) and for new brands of existing drugs (N).

Data

All data is semi-annual over the period 1971 to 1979 inclusive.

The dependent variable, price of the dominant firm, was obtained from the Drugstore and Hospital Report published

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10 A drug product is "cleared" when it is granted a Notice of Compliance by the Health Protection Branch.

11 The clinical tests required may cost the potential entrant up to 150 thousand dollars.

by IMS of Canada Ltd.[11] This report is based on a monthly survey of a sample of pharmacies and hospitals. The present study uses only data collected from pharmacies and, hence, represents wholesale price to the drug store market alone.[12] IMS collects purchase invoices from the sample and extrapolates to produce an estimate of wholesale sales for the Canadian market as a whole. Sales are reported in both dollars and units, and division of one by the other yields an average price for each drug. Because different dosage forms (i.e. 5 mg. capsules, 10 mg. tablets, etc.) and different lot sizes (i.e. lots of 1000, 100, etc.) are not strictly comparable, it was necessary to choose one particular dosage form and lot size for the dependent variable. 5 mg. tablets of Valium sold in 1000 tablet lots was chosen since this represented by far the bulk of Valium sales for the period under study. The average price per tablet was deflated by the consumer price index to produce the price in real terms.

The main advantage to using IMS data is that it is based on wholesale prices actually received rather than on published list prices. Published prices are changed

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11 IMS stands for "Inter-continental Medical Statistics". IMS data has been used in several studies of pricing in the pharmaceutical industry. See, for example, Reekie, D.W., op. cit. and also Fulda, T.K. and Dickens, P.F., "Controlling the Cost of Drugs: the Canadian Experience", Health Care Financing Review, Fall 1979.

12 Most drugs for the hospital market are purchased on a tender basis.

infrequently and price flexibility occurs mainly through variations in discount from list.[13]

The number of fringe firms (N) and their date of entry were also obtained from IMS. IMS reports data for seven fringe firms. These are Horner, Novopharm, Beecham, Nordic, ICN, Ayerst and Apotex. If a firm entered after the first three months of a half year (i.e. November 1977), its entry was recorded in the following half year (i.e. first half 1978). The variable N is number of fringe firms rather than entry by fringe firms.

Advertising data was also obtained from IMS. The data is broken out by journal and mail advertising and, advertising by sales people (detailing). IMS surveys each of the major Canadian medical journals and, using current advertising rates, determines a total expenditure for each manufacturer for each drug. Mail advertising expenditure is calculated by collecting all promotional material received by a sample of physicians across Canada. Each piece of mail is evaluated using current rates and the sample is extrapolated to a national figure. The composite journal and mail advertising expenditure reported by IMS was deflated by the consumer price index to provide a real value.

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[13] The list price of 5 mg. tablets of Valium in 100 tablet lots did not change from 1969 through June 1977 according to the "Price Book and Product Reference for Community Pharmacy" published by the Canadian Pharmaceutical Association.

The same sample of doctors record all visits by "detail" sales people. These people provide more detailed information about the products which they represent. In 1971, IMS determined, in consultation with the pharmaceutical industry, that a detail visit cost the industry 21 dollars. Unfortunately, this value was not revised by IMS for reports in subsequent years. In order to obtain a real value for detail advertising, the reported IMS figures were inflated by a wage index for salaried employees in the pharmaceutical industry[14] and then deflated by the consumer price index.

The resulting values for journal, mail and detailing were added together to produce one figure in real terms, for advertising on diazepam by fringe firms and one value for advertising on diazepam by the dominant firm.

The date of introduction of provincial substitution legislation was determined in consultation with each province. The percentage of Canadian population living in each province was determined using 1975 population data. It was felt that substitution legislation would only become effective over time as pharmacists gained confidence in substitute products.

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[14] The index was constructed using average weekly earnings for salaried employees in the pharmaceutical and medicines industry as reported in Statistics Canada #72-002. It might have been preferable to have used a wage index for "wholesale industrial sales people" but this is not collected in Canada.

Consequently, for each province, the additional effective percentage of Canadian population benefiting from substitution in each period was estimated using the equation: $E = \theta(1-\theta)^{t}S$

where E = the additional effective percentage benefiting from substitution

θ = the rate of acceptance by pharmacists

t = the number of periods since introduction of legislation (0 at date of introduction)

S = the percentage of 1975 Canadian population residing in the province.[15]

The figure for additional percentage in each period for each province was added to the total for the last period to provide a total effective percent of Canadian population benefiting from substitution in each province during each period.[16] The figures for each province were added to obtain a total Canadian figure for each period. This total Canadian figure was calculated using alternate rates of acceptance of 5%, 10% and 15% per period.

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[15] For example, assuming a per period rate of acceptance of 10% and assuming that approximately 30% of the Canadian population lives in Quebec, the Quebec figures would be 3% on introduction, 2.7% in the first period, 2.43% in the second period, etc.

[16] Again using the hypothetical Quebec example, the figures would be 3% on introduction, 5.7% in the first period, 8.13% in the second period, etc.

Wages were proxied using the wage index for production workers in the pharmaceutical and medicines industry as obtained from Statistics Canada.[17] This was deflated by the C.P.I.

Raw material costs for fringe and dominant firms were impossible to obtain since this data is held closely by the companies. Hoffman-Laroche obtains all of its bulk raw chemical from the parent company in Switzerland while those fringe firms which could be identified as compulsory licensees obtained their bulk chemical from Italy. Wholesale pharmaceutical price indices from these countries could, thus, have been used as a reasonable proxy, but complete time series were not available. The raw material costs were thus proxied by using the producer price index for "Medicinal Chemicals and Botanical Products" in the United States.[18] The index was converted to Canadian dollars and deflated by the C.P.I.

New entry by drugs in the same therapeutic class was examined using data provided by the Federal Drug Administration

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17 Statistics Canada #72-002.

18 The price index was obtained from an official of the Bureau of Labour Statistics. American SIC 3833 "Medicinal Chemicals and Botanical Products" includes "establishments primarily engaged in manufacturing bulk organic and inorganic medicinal chemicals and their derivatives, and establishments engaged in processing bulk botanical drugs and herbs".

in the United States. The FDA rates the potential therapeutic gain for each drug which it examines. More resources are devoted to examining a drug with an "important gain" rating to ensure that it is made available to the public at the earliest possible date.[19] The Ontario Drug Benefit Formulary, January 1980, was used to determine all chemicals which fall into the same therapeutic category as diazepam.[20] Using the FDA records, it was determined that no chemicals have entered this category which the FDA felt warranted an assessment of "high therapeutic gain" or "moderate therapeutic gain".[21] Consequently, this variable was dropped for the regression analysis.

Empirical Results

The ordinary least squares estimate of equation (11) is presented as regression 1 in Table I. Figures in parentheses are t-statistics. The variable denoting provincial substitution ($PROV_{10}$) is significant at the 99% level, while the variable for number of fringe suppliers (N)

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19 The FDA therapeutic gain rating has been used in several studies including Reekie, W.D., op. cit. and, Bond, R.S. and Lean, D.L., Sales Promotion and Product Differentiation in Two Prescription Drug Markets, Staff Report to the Federal Trade Commission, February 1977.

20 The Ontario Formulary lists this therapeutic category as "Psychotherapeutic Agents - Tranquilizers".

21 Two drugs entered the market which were assessed as "little or no therapeutic gain".

Table 1

1. $\ln P_D = 3.776 - .159 \ln PROV_{10} - .152 \ln N + .079 \ln AF - .826 \ln W - .434 \ln RM + .011 \ln AD$

(3.95) (2.87) (2.43) (1.55) (1.13) (.35)

$\bar{R}^2 = .97$ n = 18 D.W. = 1.58 F = 96.89

2. $\ln P_D = 4.921 - .040 T - .076 \ln PROV_{10} - .053 \ln N - .064 \ln AF + .11 \ln RM - .004 \ln AD - .04 \ln W$

(9.08) (4.63) (2.49) (3.31) (.774) (.419) (.219)

$\bar{R}^2 = .99$ n = 18 D.W. = 2.42 F = 710.94

Variable List

P_D = price of diazepam marketed by Hoffman-Laroche
N = number of fringe suppliers
AF = advertising by fringe firms
AD = advertising by dominant firms
$PROV_5$ = provincial substitution legislation constructed using 5% rate of acceptance
$PROV_{10}$ = provincial substitution legislation constructed using 10% rate of acceptance
$PROV_{15}$ = provincial substitution legislation constructed using 15% rate of acceptance
W = wage index of pharmaceutical workers
RM = raw material costs
T = time trend

is significant at the 98% level and the variable for fringe advertising is significant at the 95% level. The results indicate that doubling the number of fringe suppliers results in a drop of 15% in the price of the dominant firm. Similarily, a doubling of the percentage of Canadian population effectively benefiting from generic substitution legislation results in a 16% reduction in the price of the dominant firm. An increase of 10% in fringe advertising should result in an increase of less than 1% in the price of the dominant firm. The signs of the coefficients for these variables are in accordance with expectations developed in the theoretical section. The coefficients for wages, raw material costs and dominant firm advertising were not statistically different from zero.

As both the number of fringe suppliers and the effective percentage of population under substitution law increased over time, it is arguable that these variables are only reflective of some autonomous effect which obtained over the time period. For example, as diazepam had already been on the market for eight years prior to the study period, it could be argued that N and PROV simply reflect the possibility that diazepam was in the declining stages of its product life cycle from 1971 to 1979. This could occur for several reasons. Firstly, although there was no significant entry into the

therapeutic class, existing drugs in the class could have become more popular as tranquilizers. As well, there may have been a general movement away from tranquilizers as therapy in the treatment of certain mental problems. In effect, other therapies (such as counselling) may have provided increasing competition for diazepam over the study period. Using data provided by Fulda and Dickens,[22] it appears that the real price of diazepam fell in the U.S. over the period 1970 to 1974. As Hoffman-Laroche was the only producer in the market, this indicates that the life cycle hypothesis may be a legitimate concern. It should be noted, however, that other factors, unique to the U.S., could have been responsible for this decline.

In order to allow for the possibility of a life cycle effect, the first regression was re-estimated with the addition of a time trend which increased by a value of 1 for each observation. The results are presented as regression 2. Here again, $PROV_{10}$ and N are both highly significant and exhibit the correct signs. The time trend variable is also highly significant indicating that the life cycle hypothesis may have some validity in this application. It is notable that the addition of the time trend lowers the value of the coefficients of both $PROV_{10}$ and N indicating that part of their

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[22] Fulda and Dickens, op. cit.

earlier value may have reflected a life cycle effect. The results indicate that, over and above any autonomous effect, a doubling of the number of fringe suppliers would lead to a 5.3% fall in the price of the dominant firm. Similarily, a doubling of the percentage of population effectively under generic substitution would lead to a 7.6% drop in dominant firm price. Fringe firm advertising also proves significant in this equation but exhibits a negative coefficient. Raw material costs, dominant firm advertising and wages were all insignificant.

Separate regressions were also estimated using 5% and 15% rates of acceptance for the provincial substitution variable. The results do not differ markedly from those obtained using the 10% rate. These equations are presented as an appendix to the paper.

Policy Implications

It is important to note that any policy implications drawn from these results can only be applied to the diazepam market.[23]

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[23] The author intends to extend this analysis in the future to cover a sample of drugs in order to strenthen the policy conclusions. The sample will include both drugs which have had compulsory licenses issued against them and drugs which were not the subject of compulsory licenses.

The regression results strongly indicate that the number of fringe suppliers has had a substantial effect in lowering the price of diazepam sold by Hoffman-Laroche.

The IMS data provided evidence on 7 fringe firms. Of these, Ayerst, Nordic and Beecham did not receive compulsory licenses. These firms either obtained compulsory licenses under the name of an associated company[24] or obtained voluntary licenses from Hoffman-Laroche. If the latter is the case, it is argued that these voluntary licenses would not have been granted in the absence of the enactment of the compulsory licensing provisions. This argument is supported by the fact that, to the best of my knowledge, Hoffman-Laroche is still the only firm manufacturing diazepam in the United States where compulsory licensing does not exist.[25]

Given the existence of compulsory licensing as an alternative, Hoffman-Laroche would not have been able to impose any conditions on voluntary licensees which were not imposed on compulsory licensees by the Commissioner of Patents. Any restrictions on pricing or volume would leave these firms

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[24] A number of changes in industry ownership took place during the period under study. It proved impossible to trade these changes using conventional sources.

[25] The Red Book of drug prices in the U.S. lists Hoffman-Laroche as the only supplier in 1979.

at a disadvantage vis-à-vis the compulsory licensees. In the absence of compulsory licensing, these firms would have been refused licenses or would have been subjected to conditions which would not interfere with Hoffman-Laroche's profit maximizing strategy. Given compulsory licensing, these firms can properly be regarded as fringe firms and, indeed, owe their existence as fringe members to the compulsory licensing provisions.

It is concluded that the compulsory licensing provisions were a substantial determinant of declines in the price of diazepam produced by Hoffman-Laroche. Similarily, the results strongly indicate that provincial generic substitution legislation has contributed significantly to declines in the real price of the Hoffman-Laroche product.[26] Both of these conclusions hold up, even given the existence of a life cycle effect on the price of diazepam.[27] It appears that some life cycle influence is likely given the evidence on real American prices. The estimated coefficients in

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[26] Strictly speaking, the coefficients for N and PROV also incorporate the effects of supportive legislation such as amendments to the Trade Marks Act, publication of provincial and federal formularies etc.

[27] This conclusion is supported by the evidence of Fulda and Dickens, op. cit., who estimated that, between 1970 and 1974, the weighted average nominal price of diazepam fell by 45.9% in Canada and rose by 2.8% in the United States.

regression 2, therefore, represent a minimum estimate of the effectiveness of the government policies while those in regression 1 represent a maximum estimate.

In conclusion, it can be said that both the compulsory licensing provisions under the Patent Act, and generic substitution legislation by the provinces, have been effective in lowering the price of diazepam marketed by Hoffman-Laroche.

Appendix

3. $\ln P_D = 3.719 - .161 \ln PROV_5 + .068 \ln AF - .138 \ln N - .734 \ln W - .419 \ln RM + .011 \ln AD$

(4.42) (2.21) (2.73) (1.46) (1.18) (.36)

$\bar{R}^2 = .975$ $n = 18$ D.W. = 1.59 F = 111.44

4. $\ln P_D = 4.862 - .077 \ln PROV_5 - .038 T - .064 \ln AF - .053 \ln N + .11 \ln RM - .0048 \ln AD - .043 \ln W$

(4.65) (8.42) (3.3) (2.49) (.76) (.43) (.21)

$\bar{R}^2 = .997$ $n = 18$ D.W. = 2.44 F = 712.41

5. $\ln P_D = 3.816 - .165 \ln N + .088 \ln AF - .158 \ln PROV_{15} - .922 \ln W - .451 \ln RM + .012 \ln AD$

(3.0) (2.57) (3.56) (1.65) (1.1) (.35)

$\bar{R}^2 = .968$ $n = 18$ D.W. = 1.57 F = 86.04

6. $\ln P_D = 4.965 - .041 T - .077 \ln PROV_{15} - .065 \ln AF - .053 \ln N + .11 \ln RM - .0045 \ln AD - .05 \ln W$

(9.7) (4.63) (3.36) (2.5) (.76) (.39) (.25)

$\bar{R}^2 = .997$ $n = 18$ D.W. = 2.41 F = 710.29

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